

WHAT IS CLAIMED IS:

1. A method of treating a skin or wound infection comprising topically applying to a patient in need thereof at the site of infection an effective amount of a topical composition comprising an effective amount of lysostaphin and/or one or more lantibiotics in a pharmaceutically acceptable carrier for topical application.

2. The method of claim 1, comprising treating a wound infection selected from infected abrasions, skin or surface cuts, burns or surgical incisions or decubiti.

3. The method of claim 1, wherein said topical composition comprises from about 0.10 to about 10.0 wt% lysostaphin selected from the group consisting of wild-type lysostaphin, lysostaphin mutants, variants and fragments, synthetic lysostaphins and recombinant lysostaphins, and has proteolytic activity against pentaglycine-containing bridges in the cell wall peptidoglycan of staphylococci.

4. The method of claim 1, wherein said topical composition comprises from about 0.10 to about 10.0 wt% of one or more lantibiotics selected from the group consisting of nisin, subtilin, epidermin, gallidermin, cinnamycin, duramycin, ancovenin, and Pep 5.

5. The method of claim 4, wherein said topical composition comprises nisin and a surfactant, and/or a chelating agent and/or carvacrol.

6. The method of claim 5, wherein said chelating agent comprises EDTA.

7. The method of claim 4, wherein said topical composition comprises a recombinant nisin variant.

8. The method of claim 4, wherein said topical composition comprises nisin and lysostaphin.

9. The method of claim 1, wherein said topical composition further comprises at least one anti-infective active agent other than lysostaphin or a lantibiotic.

10. The method of claim 9, wherein each anti-infective active agent or antibacterial enzyme is selected from the group consisting of beta-lactams, polymixin, glycopeptides, mutanolysin, lysozyme, cellozyl muramidase, antibacterial antibodies and antibacterial peptides.

11. The method of claim 9, wherein said topical composition further comprises at least one of bacitracin and neomycin.

12. The method of claim 1, wherein said pharmaceutically acceptable carrier for topical application is in the form of a spray, mist, aerosol, lotion, cream, aqueous or non-aqueous solution or liquid, oil, gel, ointment, paste, unguent, emulsion or suspension.

13. The method of claim 12, wherein said pharmaceutically acceptable carrier for topical application is an oil-in-water emulsion-based cream or lotion comprising an aqueous

phase comprising ethoxylated partial glycerides of fatty acids, an oil phase comprising a hard fat, and an emulsifier that is an inverse emulsion of a water-soluble polymer in an oil phase.

14. The method of claim 13, wherein said aqueous phase comprises a skin
5 absorption promoter selected from the group consisting of DMSO and partial fatty acid glycerides.

15. The method of claim 1, wherein said topical composition is a cream formulation comprising:

10 about 0.125 to about 10 % by weight of lysostaphin and/or one or more lantibiotics;

about 2 to about 10 % by weight of SOFTISAN 378;

about 0.25 to about 3 % by weight of SOFTIGEN 767;

about 2 to about 8 % by weight of SEIGEL 305 or SIMUGEL 600;

0 to about 10% by weight of IMWITOR 308 and/or IMWITOR 742; and

15 about 70 to about 90 % by weight of water.

16. The method of claim 1, wherein said topical composition is coated on the surface of a topical applicator.

20 17. A topical composition comprising an effective amount of lysostaphin and/or or one or more lantibiotics in a pharmaceutically acceptable carrier for topical application.

18. The topical composition of claim 17, wherein the amount of lysostaphin or lantibiotic is effective to treat skin infections or infected wounds selected from infected abrasions, skin or surface cuts, burns or surgical incisions or decubiti.

5 19. The topical composition of claim 17, comprising from about 0.10 to about 10.0 wt% of lysostaphin selected from the group consisting of wild-type lysostaphin, lysostaphin mutants, variants and fragments, synthetic lysostaphins and recombinant lysostaphins, and has the proteolytic activity against pentaglycine-containing bridges in the cell wall peptidoglycan of staphylococci.

10 20. The topical composition of claim 17, comprising from 0.10 to about 10.0 wt% of one or more lantibiotics selected from the group consisting of nisin, subtilin, epidermin, gallidermin, cinnamycin, duramycin, ancovenin, and Pep 5.

15 21. A topical composition according to claim 20, comprising nisin, and a surfactant, or a chelating agent or carvacrol.

 22. The topical composition of claim 21, wherein said chelating agent is EDTA.

20 23. The topical composition of claim 20, comprising a recombinant nisin variant.

 24. A topical composition according to claim 20, comprising lysostaphin and nisin.

25. The topical composition of claim 17, further comprising at least one anti-infective active agent other than lysostaphin or a lantibiotic.

26. The topical composition of claim 25, wherein each anti-infective active agent is selected from the group consisting of beta-lactams, polymixin, glycopeptides, mutanolysin, lysozyme, cellozyl muramidase, antibacterial antibodies and antibacterial peptides.

27. The topical composition of claim 25, wherein said anti-infective active agent comprises at least one of bacitracin and neomycin.

28. The topical composition of claim 17, wherein said pharmaceutically acceptable carrier for topical application is in the form of a spray, mist, aerosol, lotion, cream, aqueous or non-aqueous solution or liquid, oil, gel, ointment, paste, unguent, emulsion or suspension.

29. The topical composition of claim 28, wherein said pharmaceutically acceptable carrier for topical application is an oil-in-water emulsion-based cream or lotion comprising an aqueous phase comprising ethoxylated partial glycerides of fatty acids, an oil phase comprising a hard fat, and an emulsifier that is an inverse emulsion of a water-soluble polymer in an oil phase.

30. The topical composition of claim 29, wherein said aqueous phase comprises a skin absorption promoter selected from the group consisting of DMSO and partial fatty acid glycerides.

31. A topical composition according to claim 17, in the form of a topical cream comprising:

about 0.125 to about 10 % by weight of lysostaphin and/or one or more lantibiotics;

about 2 to about 10 % by weight of SOFTISAN 378;

5 about 0.25 to about 3 % by weight of SOFTIGEN 767;

about 2 to about 8 % by weight of SEIGEL 305 or SIMUGEL 600;

0 to about 10% by weight of IMWITOR 308 and/or IMWITOR 742; and

about 70 to about 90 % by weight of water.

10 32. The topical composition of claim 17, coated on the surface of a topical applicator.

33. A method of decolonizing skin pathogen populations comprising topically applying to a patient in need thereof at a site requiring decolonization an effective amount of
15 the topical composition of claim 17.

34. The method of claim 33, wherein said topical composition comprises from about 0.10 to about 10.0 wt% of lysostaphin selected from the group consisting of wild-type lysostaphin, lysostaphin mutants, variants and fragments, synthetic lysostaphins and
20 recombinant lysostaphins, and has proteolytic activity against pentaglycine-containing bridges in the cell wall peptidoglycan of staphylococci.

35. The method of claim 33, wherein said topical composition comprises from about 0.10 to about 10.0 wt% of one or more lantibiotics selected from the group consisting of nisin, subtilin, epidermin, gallidermin, cinnamycin, duramycin, ancovenin, and Pep 5.

5 36. The method of claim 35, wherein said topical composition comprises nisin and a surfactant, or a chelating agent or carvacrol.

37. The method of claim 36, wherein said chelating agent comprises EDTA.

10 38. The method of claim 35, wherein said topical composition comprises a recombinant nisin variant.

39. The method of claim 35, wherein said topical composition further comprises lysostaphin.

15 40. The method of claim 33, wherein said topical composition further comprises at least one anti-infective active agent other than lysostaphin or a lantibiotic selected from the group consisting of beta-lactams, polymixin, glycopeptides, mutanolysin, lysozyme, cellozyl muramidase, antibacterial antibodies and antibacterial peptides.

20 41. The method of claim 33, wherein said topical composition further comprises at least one of bacitracin and neomycin.

42. The method of claim 33, wherein said pharmaceutically acceptable carrier for topical application is in the form of a spray, mist, aerosol, lotion, cream, aqueous or non-aqueous solution or liquid, oil, gel, ointment, paste, unguent, emulsion or suspension.

5 43. The method of claim 42, wherein said pharmaceutically acceptable carrier for topical application is an oil-in-water emulsion-based cream or lotion comprising an aqueous phase comprising ethoxylated partial glycerides of fatty acids, an oil phase comprising a hard fat, and an emulsifier that is an inverse emulsion of a water-soluble polymer in an oil phase.

10 44. The method of claim 43, wherein said aqueous phase comprises a skin absorption promoter selected from the group consisting of DMSO and partial fatty acid glycerides.

15 45. The method of claim 33, wherein said topical composition is a cream formulation comprising:

about 0.125 to about 10 % by weight of lysostaphin and/or one or more lantibiotics;

about 2 to about 10 % by weight of SOFTISAN 378;

about 0.25 to about 3 % by weight of SOFTIGEN 767;

about 2 to about 8 % by weight of SEIGEL 305 or SIMUGEL 600;

20 0 to about 10% by weight of IMWITOR 308 and/or IMWITOR 742; and

about 70 to about 90 % by weight of water.

46. The method of claim 33, wherein said topical composition is coated on the surface of a topical applicator.

47. An oil-in-water emulsion-based topical cream or lotion composition comprising an aqueous phase comprising ethoxylated partial glycerides of fatty acids, an oil phase comprising a hard fat, an emulsifier that is an inverse emulsion of a water-soluble polymer in an oil phase, and an effective amount of one or more anti-infective active agents in said aqueous phase or said oil phase.

48. The topical composition of claim 47, wherein said aqueous phase comprises a skin absorption promoter selected from the group consisting of DMSO and partial fatty acid glycerides.

49. The topical composition of claim 47, coated on the surface of a topical applicator.

50. The topical composition of claim 47, wherein said emulsifier is an inverse emulsion of polyacrylamide in liquid paraffin.

51. The topical composition of claim 47, wherein at least one anti-infective active agent is selected from the group consisting of beta-lactams, polymixin, glycopeptides, mutanolysin, lysozyme, cellozyl muramidase, antibacterial antibodies and antibacterial peptides.

52. The topical composition of claim 47, wherein each anti-infective active agent is selected from the group consisting of lysostaphin, lantibiotics, bacitracin and neomycin.

53. The topical composition of claim 51, wherein said anti-infective active agents comprise lysostaphin and nisin.

54. The topical composition of claim 47, in the form of a topical cream comprising:

5 wherein said topical composition is a cream formulation comprising:

about 0.125 to about 10 % by weight of lysostaphin and/or one or more lantibiotics;

about 2 to about 10 % by weight of SOFTISAN 378;

about 0.25 to about 3 % by weight of SOFTIGEN 767;

about 2 to about 8 % by weight of SEIGEL 305 or SIMUGEL 600;

10 0 to about 10% by weight of IMWITOR 308 and/or IMWITOR 742; and

about 70 to about 90 % by weight of water.